

REMARKS

This paper is filed responsive to the Office Action mailed March 18, 2010. Claims 1, 4-24 are pending in the application. Claims 2, 3 and 25-50 have been canceled. Claims 1, 4-9, 11-13, 16, 19, 22 and 24 are amended. No new matter is added.

Claims 1, 2, 4, 5, 10, 19, 20, 23, 24, 25, 26 stand rejected under 35 U.S.C. 102(a) as being anticipated by US 6,640,127 (Kosaka). Applicants traverse the rejection.

Claim 1 claims a method for generating a registered image of a body part of a patient for use in a computer aided surgical procedure, the method including the steps of:

attaching a first marker detectable by a tracking system to the body part prior to any surgical steps of the surgical procedure, ***the tracking system having a reference frame***;

using an imaging system having a second marker attached thereto in a known positional relationship relative to the imaging plane of the imaging system to capture at least a first image of at least a portion of the body part using an imaging system;

during the capturing step, using the tracking system to detect the position of the first marker and the second marker in the reference frame;

obtaining an indication of the position of the first image relative to the reference frame of the tracking system using the detected position of the second marker and the known positional relationship between the second marker and the imaging plane; and

determining a mapping to bring the first image into registration with the position of the body part ***in the reference frame*** using the detected position of the first marker.

Among other elements, Applicants have amended claim 1 to add the steps of “using an imaging **system having a second marker attached thereto** in a known positional relationship relative to the imaging plane of the imaging system to capture at least a first image of at least a portion of the body part using an imaging system” and “obtaining an indication of the position of the first image relative to the reference frame of the tracking **system using the detected position of the second marker and the known positional relationship between the second marker and the imaging plane**”.

Kosaka describes a reference frame in the form of spectacles having a plurality of markers worn by a patient. The markers are made of a material that can be imaged by X-ray or MRI scan. See Kosaka, col 2:48-51; col 12:54-13:10. A surgical operation navigation unit (Fig. 5, element 24) is used together with an imaging unit (Fig. 5, element 22). Coordinate systems are defined for surgical instruments (E), for captured images (P) and for real space (W) in the operating room. Kosaka, col 14:3-49. The different coordinate systems can be registered using various different types of transformation matrices. The image coordinate system (P) is registered with the real space coordinate system (W) in a process referred to as Operative Calibration. Kosaka, col 15:33-35. Coordinate transformation parameters wH_p define the coordinate transformation from the image coordinate system to the real world coordinate system. See Kosaka, col 15:67-16:3 and Fig. 7, element 32.

The reference frame is worn by the patient and the patient is imaged so as to capture the markers in the image. Fig 13, step S11. Then the positions of the markers in the imaging coordinate system are determined. Fig. 13, step S12. The positions of the markers are detected in the real world coordinate system using a position sensing system. Fig. 13, step S13. Then the image can be aligned with the real world coordinate system using the marker positions captured in the image and the marker positions determined by the position sensing system. Fig. 13, step S14 and col. 19:7-14. Hence, this approach determines the transformation required between an imaging system coordinate system and a different, real world coordinate system in order to register the patient image in the real world.

The second embodiment shown in Figure 19 also includes determining "coordinate transformation parameters for transforming the coordinate system 30 for the real space into the coordinate system 29 for the image, Kosaka, col 24:20-22, and thus also involves a transformation between different coordinate systems and not a transformation within a single tracking system coordinate system.

In the present claimed invention, the position of the image in the reference frame of the tracking system and the position of the body part of the patient in the same reference system of the tracking system are determined. The claimed invention then requires the step of determining a mapping to bring the first image into registration with the position of the body part **in the same reference frame** (that of the tracking system) using the detected position of the

first marker rather than determining a mapping between different reference systems (the image and the real world) as described in Kosaka.

Further, as the Examiner recognized at page 3 of the outstanding Office Action, Kosaka fails to disclose the use of an imaging device that has a marker attached to it. As a result, for the foregoing reasons, Kosaka does not describe the claimed invention, and Applicants request the Examiner to withdraw the rejection.

Claims 3, 13, 14, 15, 16, 21, 22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kosaka in view of US 2002/0188194 (Cosman). Applicants traverse the rejection as the combination of Cosman and Kosaka do not describe the claimed invention.

Cosman also fails to describe the steps of the invention claimed in claim 1 as Cosman fails to describe at least the last step of claim 1—the step of “determining a mapping to bring the first image into registration with the position of the body part in the reference frame using the detected position of the first marker”. Instead, Cosman employs a conventional imaging step as part of its surgical procedure. Prior to the patient being located in the treatment space, the patient is imaged and that image is stored to be used when the patient is in the treatment space. During the imaging step, the patient has markers attached to him or her and those markers are used as reference points and are located within a coordinate system. As explained in Cosman,

Recapitulating to some extent, it will be understood that as explained above, during an initial procedure, scan data is taken from the patient, as by a CT or MRI scanner and stored in the imager 35. In accordance with one operating format, the scan data may comprise slice data, three-dimensionally representing a portion of the patient P in scan data space. Of course, scan data space is distinct from camera data space, compatibility being attained by translating to a common coordinate space. Transformations, using well-known techniques of the art, are accomplished by referencing certain markers, e.g., markers 20, 21, 23 and 24 which are located on the patient P and identify reference points in both space coordinates.

As indicated, during the scanning process, the positions of the index markers 20, 21, 23 and 24 on the patient P are determined in the coordinate space of the scanner (CT or MRI, scan space)

employed to generate the image scan data. For example, for CT scanning, graphic reference markers can be radiopaque markers placed on the skin at positions indicated by index markers 20, 21, 23, and 24. ... Knowing the coordinates in the scan space, and the coordinate locations of anatomical objects relative to them (markers 20, 21, 23 and 24) the target sites to be radiated are determined relative to the index points defined by the markers 20, 21, 23 and 24. As indicated, image scan data for the index-marked positions is stored in the imager or image data storage memory 35 for use by the planning system 36 and the computer 37.

In the treatment planning computer 36, positions are determined for the markers 20, 21, 23 and 24, relative to the anatomy of the patient P and the selected internal anatomical targets. Accordingly, target coordinates within a volume are resolved in the scan data coordinate system.

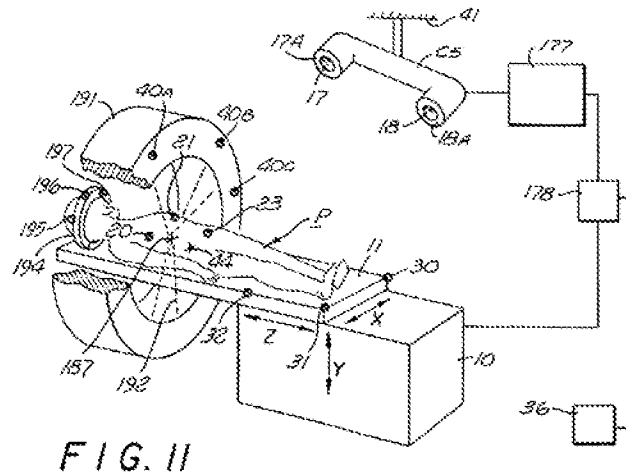
The specific locations of the points identified by the markers 20, 21, 23 and 24 also are determined in camera space by the camera system C while the patient P is on the couch F. ***Thus, identical reference locations are provided in the two coordinate systems (scan and camera) enabling data transformations as well known in the computer graphics field.***

Cosman, ¶¶ 38- 41. Thus, the patient is scanned in the scan coordinate system and the markers' positions are defined and both the image and positions are stored. It is important to note that during this initial procedure, the position of the device that performs the scanning—the CT or MRI—is not tracked. Following the initial imaging step, the patient is later positioned in the operating theatre, the position of the markers (or reference locations) are then determined in the referencing system of the camera in the operating theatre. See Cosman, ¶ 41. "Thus, identical reference locations are provided in the two coordinate systems (scan and camera) enabling data transformations as well known in the computer graphics field." Cosman, ¶ 41. The position of the markers on the patient's body are then defined relative to the treatment apparatus, enabling the surgeon to point the beam of the collimeter at the target.

Thus this Cosman embodiment, like Kosaka, does not describe the step of "determining a mapping to bring the first image into registration with the position of the body part in the reference frame using the detected position of the first marker." There are two reference

frames in Cosman—the scanning reference system (while imaging) and the camera reference system (during the operating, real world theatre).

The embodiment depicted in Figure 11 of Cosman is described similarly to the prior embodiments of Cosman: “FIG. 11 illustrates another embodiment in accordance with the present invention **wherein the use of camera tracking of the patient and apparatus is associated with an image scanning apparatus as described previously.**” The only difference is that additional scanning may be performed during the surgical theatre.



As with the prior embodiments of Cosman, in this embodiment, the patient initially is scanned and a target 44 is identified to be treated. See Cosman, ¶ 104. It is understood that it may be desirable to rescan the tissue near the historic target to determine whether the tissue has changed since the historical target was identified. The imaging device 191 is tracked using markers 40A, 40B and 40C so that the device can be moved relative to markers on the patient's body (either 20, 21 and 23, or 195, 196, 197). The patient may be positioned on a movable bed 11 just for this purpose.

Again, as in the prior embodiments, there is no mapping step of determining a mapping to bring the first image into registration with the position of the body part **in the reference frame** (the scanning reference frame) using the detected position of the first marker. Where Cosman scans for the position of the reference markers located on the imaging system, Cosman is operating in the real world, camera reference system, not in the imaging reference

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system. As a result, there is no need to determine a mapping to bring the first image into registration with the position of the body part in the reference frame. Applicants thus submit that the combination of Cosman and Kosaka do not describe the claimed invention, and request the Examiner to withdraw the rejection.

Claims 6, 7, 9, 11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kosaka in view of US 2002/0198451 (Carson). Claim 12 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Kosaka in view of US 2003/0023161 (Govari). Applicant traverses the rejection. Claim 17 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Kosaka in view of Cosman as applied to claim 14 above, and further in view of US 6,144,875 (Schweikard). Claim 18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Kosaka in view of Cosman as applied to claim 14 above, and further in view of US 6,206,566 (Schuetz). Applicant traverses the rejections.

Claims 6, 7, 9, 11, 12, 17 and 18 depend at least indirectly from independent claim 1 and Applicant submits that these claims are patentable at least because claim 1 is patentable over the cited prior art.

Please charge any fee associated with the prosecution of this application to Deposit Account No. 10-0750.

Applicants submit that the application is presently in condition for allowance and request favorable reconsideration and early notice of allowance. If it would speed prosecution, the Examiner is encouraged to contact the undersigned attorney by telephone.

Respectfully submitted,

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